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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/842745	FANSLOW
	Examiner	Art Unit
	GIMBEL	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 10/12/02; 2/21/03; 6/24/03

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-22

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5, 20-22

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1-4, 6-19

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's reaffirmation the election with traverse of the species CD40L / soluble CD40L as the CD40 binding agent and CD30L as the additional agent.

Applicant further elect breast cancer as the species of tumor or precancerous cell type in Paper No. 14, filed 6/24/03.

Claims 1-4 and 6-19 are under consideration in the instant application.

Claims 5, 20-22 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species.

2. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c).A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions,Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, (5), 6-12 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. In evaluating the facts of the instant case, the following is noted:

It has been art-recognized experience that immunotherapy for cancer has been limited. Results obtained under controlled conditions and in inbred animals often differ from the clinical response obtained in patients. This applies in particular to strategies based on immune responses, including strategies drawn to cancer therapy. Concerning animal models, the response of animals to chemotherapy, radiation and surgery is generally predictive of their effect in human patients. Tumor burden and antigenic drift continue to present serious burdens for successful cancer therapy in vivo. Tumors are classified as immunogenic or non-immunogenic, solid or hematological in nature. Effective cancer strategies should be design to deal effectively with the nature of each of these classifications. For experimental antitumoral immunization in animals, one usually immunizes a normal animal and the effect is evaluated by the resistance to a tumor cell. For human patients, one would have to stimulate immune defense or organisms that have often carried a large tumor cell challenge.

With respect to "treating a precancerous subject" (claims 1-4, (5), 6-12), there is insufficient and guidance and direction for enabling the skilled artisan to choose those "precancerous subjects" that would be subjected to combination photodynamic and CD40L therapy. It has not been standard practice by the skilled artisan to treat precancerous subjects. The skilled artisan does not generally treat a patient with a therapeutic regimen to treat cancer prior to the diagnosis of cancer itself.

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective cancer therapies for treating precancerous subjects, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods to use combination photodynamic and CD40L combination therapy to treat precancerous subjects, commensurate in scope with the claimed invention.

With respect to the use of CD30L (claim 3), it is noted that specification discloses that CD30L may be administered concurrent with administering CD40 binding protein.

As set forth in the prior art rejection below, Goodwin et al. teach that CD30L-conjugates can be used to treat lymphoid malignancies which express CD30 (see entire document, particularly column 11, paragraphs 3-5 to column 12, paragraphs 1-2). In addition, Goodwin et al. teach that unlabeled CD30L may be used in treating large cell anaplastic lymphoma (see column 17-18, overlapping paragraph; column 12, paragraph 4). Goodwin et al. also teach that CD30L may be used in combination with additional agents effective in treating malignancies characterized by $CD30^+$ cells (see column 17-18, overlapping paragraph).

However, the instant specification appears lacking in the teachings of how to make and use CD30L to treat tumors, broadly encompassed by the claimed methods. For example, the instant specification does not appear to distinguish the use of CD30L in the context of CD30 expressing tumor. Also, the instant specification does not appear to teach conjugating CD30L with a therapeutic agent to treat CD30 expressing tumor cells. The instant specification does not appear to distinguish treating large cell anaplastic lymphoma with unlabeled CD30L versus treating CD30 expressing tumors with CD30L conjugates.

In addition, Lynch et al. teach CD40L (page 4, columns 1-2, overlapping paragraph; page 6, column 2, paragraph 1; page 8, column 1, paragraph 1) as well as CD30 ligand antagonists (page 4, column 2, paragraph 3; page 6, column 2, paragraph 3; page 8, column 1, paragraph 1) to augment immune responses, including antitumor responses (e.g. page 7, columns 1-2). The CD30 ligand antagonists disclosed by Lynch et al. include CD30L-specific antibodies and soluble CD30 which is distinguished from the claimed methods of treating tumor bearing subjects and precancerous subjects with CD30L itself.

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective cancer therapies for treating tumor bearing subjects and precancerous subjects, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed methods and absent working examples providing evidence which is reasonably predictive that the claimed methods to use combination photodynamic, CD40L and CD30L combination therapy to treat cancer, commensurate in scope with the claimed invention. .

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 4 and 6-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Curry et al. (US 2002/0022032) AND/OR Hunt et al. (US 2003/0008857) in view of Armitage et al. (U.S. Patent No. 5,674,492) AND/OR Lynch et al. (US 2003/0165531) and further in view of Armitage et al. (U.S. Patent No. 6,410,711.

Curry et al. teach the combination of photodynamic treatment and immunoadjuvants, including cytokines (page 5, column 2 - page 7 in the treatment of tumors, including melanoma, breast cancer, colon cancer and prostate cancer (page 4, column 2, paragraph 3) (see entire document, including Description of the Related Art, Summary of the Invention, Detailed Description of the Invention and Claims).

Hunt et al. teach the combination of photodynamic treatment and apoptosis-inducing agents (see entire document, including Description of the Related Art, Summary of the Invention, Detailed Description of the Invention and Claims).

Curry et al. and Hunt et al. differ from the claimed methods by not disclosing the use of CD40L or CD30L as an adjuvant or apoptosis-inducing agent.

Armitage et al. teach methods of treating neoplastic diseases, including B lymphomas, melanoma and carcinomas that express CD40 with a CD40 binding protein, including the CD40L comprising Fc domain and leucine zippers of the instant claims (see CD40L on columns 5-10) (see entire document, including Claims). In addition to inhibiting various B cell lymphomas directly, Armitage et al. teach that it may be necessary to conjugate CD40 binding proteins with toxins or radioactive compounds (see column 12, Prevention or Treatment). In addition, Armitage et al. teach that the inventive methods may be used in conjunction with other therapies appropriate for afflicted individuals, including chemotherapy, radiation therapy and immunotherapy (see column 12, Prevention or Treatment).

Lynch et al. teach CD40L (page 4, columns 1-2, overlapping paragraph; page 6, column 2, paragraph 1; page 8, column 1, paragraph 1) as well as CD30 ligand antagonists (page 4, column 2, paragraph 3; page 6, column 2, paragraph 3; page 8, column 1, paragraph 1) to augment immune responses, including antitumor responses (e.g. page 7, columns 1-2)

Although Armitage et al. and Lynch et al. Are silent about the exact sequences of oligomeric CD40L, including oligomeric CD40-L which comprises Fc domains and leucine zippers, these references teach the same oligomeric CD40L encompassed by the claimed invention.

Although Armitage et al. ('492) teaches the CD40L employed in the claimed methods, Armitage et al. ('492) does not teach the specific sequences. Armitage et al. ('492) does teach that CD40L sequences can be found in USSN 07/969,703. Armitage et al. (U.S. Patent No. 6,410,711) is a child USSN application of USSN 07/969,703. Armitage et al. ('711) teach the sequences including those that comprise Fc domains and leucine zippers for therapeutic purposes (See entire document, including Detailed Description and Examples).

Similarly, Lynch et al. refer to PCT Publications WO 93/08207 and WO 96/40918 for sequences associated with the CD40 binding protein CD40L (see page 4, columns 1-2, overlapping paragraph). These PCT publications provide the same or nearly same teachings as Armitage et al. (U.S. Patent No. 6,410,711) with respect to the sequences associated with CD40 binding protein CD40L.

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Armitage et al. or Lynch et al to those of Curry et al. or Hunt et al. to substitute the immunostimulating properties of CD40L to a broad range of tumors as taught by Armitage et al. and Lynch et al. or the apoptotic properties of CD40L to certain types of CD40-expressing tumors as taught by Armitage et al. as the immunoadjuvant in the combination tumor therapy taught by Curry et al. or as the apoptotic agent as taught by Hunt et al.

According to Curry et al. or Hunt et al., a person of ordinary skill in the art would have been motivated to produce this resultant combination therapy with photodynamic therapy, since Curry et al. and Hunt et al. teach the advantages of combination therapy with immunostimulatory agents or apoptotic agents at the time the invention was made.

Similarly, both Armitage et al. and Lynch et al. teach combination antitumor therapy with CD40L as an immunostimulant or as an apoptotic agent. Given the properties of CD40L as an immunostimulant or apoptotic agent as taught by Curry et al. and Hunt et al., which is consistent with these properties with the teachings of Curry et al. and Hunt et al., a person of ordinary skill in the art would have recognized that the combination therapy to treat tumors with PDT and CD40L would have had a reasonable expectation of success at the time the invention was made.

It is noted that the ordinary artisan would have applied CD40L as an immunostimulant or as an apoptotic agent would have depended on the type of tumor to be treated. While the immunostimulant or adjuvant properties of CD40L would have been applied broadly against a number of tumor types, including B lymphomas, melanomas and carcinomas, the apoptotic properties of CD40L would have been limited to certain types of CD40-expressing cell types, as taught by Armitage et al.

The immunostimulant or adjuvant properties of CD40L would have been expected to stimulate various immune responses, including memory CTL to said tumor, given the teachings of both Armitage et al. and Lynch et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute CD40L as the immunoadjuvant or apoptotic agents in the teachings of combined photodynamic therapy of Curry et al. or Hunt et al. In therapeutic regimens to treat tumor-bearing subjects. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Curry et al. (US 2002/0022032) AND/OR Hunt et al. (US 2003/0008857) in view of Armitage et al. (U.S. Patent No. 5,674,492) AND/OR Lynch et al. (US 2003/0165531) and further in view of Armitage et al. (U.S. Patent No. 6,410,711
as applied to claims 1, 2, 5 and 6-12 above and further in view of
Goodwin et al. (U.S. Patent No. 6,143,869).

The teachings of Curry et al. (US 2002/0022032) AND/OR Hunt et al. (US 2003/0008857) in view of Armitage et al. (U.S. Patent No. 5,674,492) AND/OR Lynch et al. (US 2003/0165531) and further in view of Armitage et al. (U.S. Patent No. 6,410,711. differ from the claimed invention by not teaching the use of CD30L as an additional active agent.

Goodwin et al. teach that CD30L-conjugates can be used to treat lymphoid malignancies which express CD30 (see entire document, particularly column 11, paragraphs 3-5 to column 12, paragraphs 1-2). In addition, Goodwin et al. teach that unlabeled CD30L may be used in treating large cell anaplastic lymphoma (see column 17-18, overlapping paragraph; column 12, paragraph 4). Goodwin et al. also teach that CD30L may be used in combination with additional agents effective in treating malignancies characterized by $CD30^+$ cells (see column 17-18, overlapping paragraph). Goodwin et al. also teach that CD30L can stimulate proliferation of T cells (See Analysis of Biological Activities of CD30L in Example 8 in columns 30-31 in Example 13, in columns 34-36).

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Goodwin et al. in combination with teachings of Armitage et al. or Lynch et al to those of Curry et al. or Hunt et al. to substitute the immunostimulating properties of CD40L to a broad range of tumors as taught by Armitage et al. and Lynch et al. as the additional antitumor agent as taught by Curry et al. or as the apoptotic agent as taught by Hunt et al. According to Curry et al. or Hunt et al., a person of ordinary skill in the art would have been motivated to produce this resultant combination therapy with photodynamic therapy, since Curry et al. and Hunt et al. teach the advantages of combination therapy with antitumor agents or apoptotic agents at the time the invention was made. Similarly, both Armitage et al. and Lynch et al. teach combination antitumor therapy with CD40L as an immunostimulant. Given the properties of CD40L as an immunostimulant or apoptotic agent as taught by Curry et al. and Hunt et al. and the consistency with these properties with the teachings of Curry et al. and Hunt et al., a person of ordinary skill in the art would have recognized that the combination therapy to treat tumors with PDT and CD30L as an antitumor agent (apoptotic agent or CD30L-conjugate) in combination with CD40L would have had a reasonable expectation of success at the time the invention was made. It is noted that the ordinary artisan would have applied CD40L as an immunostimulant or as an apoptotic agent would have depended on the type of tumor to be treated. The immunostimulant or adjuvant properties of CD40L would have been applied broadly against a number of tumor types, including B lymphomas, melanomas and carcinomas. The immunostimulant or adjuvant properties of CD40L would have been expected to stimulate various immune responses, including memory CTL to said tumor, given the teachings of both Armitage et al. and Lynch et al. The CD30L, including conjugates of CD30L would have been expected to treat CD30 expressing tumor cells.

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute CD40L as the immunoadjuvant along with the CD30L (e.g. apoptotic agents or conjugate) in the teachings of combined photodynamic therapy of Curry et al. or Hunt et al. In therapeutic regimens to treat tumor-bearing subjects. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. In the interest of compact prosecution and given the election of breast cancer, the following rejection is applied even though breast cancer is not a specific limitation of the current claims.

Claims 1, 2, 4 and 6-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Curry et al. (US 2002/0022032) AND/OR Hunt et al. (US 2003/0008857) in view of Armitage et al. (U.S. Patent No. 5,674,492) AND/OR Lynch et al. (US 2003/0165531) and further in view of Armitage et al. (U.S. Patent No. 6,410,711 as applied to claims 1, 2,4 and 6-12 and further in view of Hirano et al. (Blood 93: 2999-3007, 1999).

It is note that the prior art rejection above would apply to the use of CD40L as an immunostimulant in the treatment of a broad range of tumor types, including breast cancer.

Also, it was noted above that Curry et al. teach the combination of photodynamic treatment and immunoadjuvants, including cytokines (page 5, column 2 - page 7 in the treatment of tumors, including melanoma, breast cancer, colon cancer and prostate cancer (page 4, column 2, paragraph 3) (see entire document, including Description of the Related Art, Summary of the Invention, Detailed Description of the Invention and Claims).

Hirano et al. teach that CD40L can lead to decreased viability due to increased apoptosis of breast carcinoma cells (see entire document, including the Abstract, Results and Discussion). In addition, Hirano et al. teach the treatment of tumor bearing SCID mice with CD40L resulted in significant increases in survival, which would indicated that CD40L would be of clinical use to inhibit human breast carcinoma growth (see Abstract, Results and Discussion)

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Hirano et al.. in combination with teachings above that CD40L can serve as an apoptotic agent to various cancer cells, including breast carcinoma cells as well.

One of ordinary skill in the art at the time the invention was made would have been motivated to select CD40L as an apoptotic agent in the treatment of breast carcinoma in combination with photodynamic treatment as taught by Hunt et al. to treat cancer. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 22, 2003